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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/522,074  
Filing Date: July 08, 2005  
Appellant(s): SLEEP, DARRELL

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Michael W. Krenicky  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9/3/10 appealing from the Office action mailed 9/3/10.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

A listing of evidence relied upon that has been provided by the appellant is complete. Office would like to add the currently pending US application 12/401,241 (US 2009/0227775 A1) as a supporting evidence to rebut appellant's arguments.

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8, 10, 11, 20-23, 57, 58 and 64-82 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hauser (US 2006/0241027).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In the instant application, Appellant claims a polypeptide comprising (i) a leader sequence, the leader sequence comprising (a) an albumin secretion pre sequence having at least 60% sequence identity to SEQ ID NO: 28, and (b) the following motif: -X1-X2-X3-X4-X5- where X1 is phenylalanine, tryptophan, or tyrosine, X2 is isoleucine, leucine, valine, alanine or methionine, X3 is leucine, valine, alanine or methionine, X4 is serine or threonine and X5 is isoleucine, valine, alanine or methionine; and (ii) a mature desired protein.

Claim as recited implies that the instant polypeptide comprises: i) a leader sequence that comprises an albumin secretion pre sequence having at least 60% sequence identity to SEQ ID

NO: 28, ii) a peptide motif -X1-X2-X3-X4-X5- wherein the variables are defined as shown above and iii) a mature protein.

Hauser discloses the following polypeptide sequence (Figure 2, SEQ ID NO 37)

**MKWVFIVSILFLFSSAYS**RS LDKRWQENEQKITALLEQQAQ IQQEKNEYELQKLDKWSLW  
EWFGGSGGSGGSGGSDAH KSEVAHRFKDLGEENFKALV LIAFAQYLQQCPFEDHVKLV  
NEVTEFAKTCVADESAENC DKSLHTLFGDKLCTVATLRET YGEMADCCAKQEPERNECF  
QHKDDNPNLPLRVRPEVDVM CTAFHDNEETFLKKYLYEIA RRHPYFYAPELLFFAKRYKA  
AFTECCQAADKAACLLPKLD ELRDEGKASSAKQRLKCSAL QKFGERAFAKAWAVARLSQRF  
PKAEFAEVSKLVTDLTQVHT ECCHGDLLECCADDRADLAKY ICENQDSISSKLECCCKEPL  
LEKSHCIAEVENDEMPADLP SLAADFVESKDVCKNYAEAK DVFLGMFLYEYARRHPDYSV  
VLLLRLLAKTYETTLKCCAA ADPHECYAKVFDEFKPLVEE PQNLIKQNCLEFQGLGEYKF  
QNALLVRYTKKVPQVSTPTL VEVSRNLGKVGSKCKKHEPA KRMPCAEDYLSVVLNQLCVL  
HEKTPVSDRVTKCCTESLVN RRPCFSALEVDETYVPKEFN AETFTFHADICTLSEKERQI  
KKQTALVELVKHKPKATKEQ LKAVMDDFAAFVEKCKADD KETCFAEEGKKLVAAASQAAL GL

The above disclosed polypeptide by Hauser comprises of peptide

**MKWVFIVSILFLFSSAYS** that reads on the SEQ ID NO: 28 of the instant application and the sequence **FIVSI** corresponds to the motif -X1-X2-X3-X4-X5- wherein X1= Phe (F), X2 = Ile (I), X3= Val (V), X4= Ser (S) and X5 =Ile (I) hence reads on instant claims 1- 8, 11, 57, 58, 64-71, 74-82. The polypeptide of Hauser is a albumin-fusion protein and hence it is a non-naturally occurring protein which is also a mature protein. This reads on instant claim 72 that recites heterologous. The polypeptide **MKWVFIVSILFLFSSAYS** which corresponds to instant SEQ ID NO: 28 is part of the leader sequence which is fused at its N-terminal end of the desired protein by its C-terminal amino acid and hence reads on the instant claim 20. Hauser also discloses that the albumin fusion protein of the invention is comprises at least a fragment or variant of a human

serum albumin [0067] and hence reads on the instant claims 22 and 23. Hauser also discloses that invention is directed to proteins containing polypeptides at least 60-99% identical to a reference polypeptide sequence, e.g., a albumin fusion protein of the invention [0112]. This further reads on the instant claims 1, 22, 66-71 and 76-81.

#### **(10) Response to Argument**

Appellant argues that the 102(e) prior art citation of Hauser, US PGPUB 2006/0241027 A1 (published 10/26/2006) that is derived from PCT/IB03/00434 (published 08/14/2003) that is derived from the provisional US application 60/355,547 (dated 2/7/2002) is not a proper 102(e) reference as the provisional application lacks written description support for the instantly claimed SEQ ID NO: 28. Applicants further argue that the instant application which is derived from the national stage PCT/GB03/03273 (published 01/29/2004) is further derived from the foreign priority document United Kingdom GB 0217033.0 (filing date 08/23/2002) supports the invention as the foreign priority document has written description support for the instantly claimed SEQ ID NO: 28.

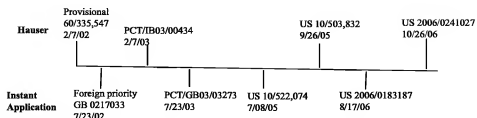
Appellant further states that the instant claims 1 and 57 are not anticipated by Hauser based on the aforementioned argument that the provisional US application 60/355,547 lacks written description support to the instant sequence claimed in the instant application. Appellant states that the foreign priority document GB 0217033.0 (filing date 08/23/2002) has an earlier priority date when compared to the IB03/00434 (published 08/14/2003) of Hauser that discloses the instantly claimed peptide sequence SEQ ID NO: 28 as SEQ ID NO: 37. Hence the 102(e) rejection is improper.

Appellant also argues that instead of reviewing the provisional application of Hauser, office used the MPEP section 2136.02 in response to after-final reply submitted on 2/3/2010 that states, "35 U.S.C. 102(e) is explicitly limited to certain references "filed in the United States before the invention thereof by the applicant" (emphasis added). Foreign applications' filing dates that are claimed (via 35 U.S.C. 119(a) -(d), (f) or 365(a) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may not be used as 35 U.S.C.102(e) dates for prior art purposes. This includes international filing dates claimed as foreign priority dates under 35 U.S.C. 365(a). Therefore, the foreign priority date of the reference under 35 U.S.C. 119(a)-(d) f), and 365(a) cannot be used to antedate the application filing date".

Appellant argues that in the instant case whether Hauser can be a prior art in light of the fact that Hauser fails to provide written description support for the instantly claimed peptide sequence in the provisional application filed on 2/7/2002. Appellant further argues that the office has not provided evidence as to where the subject matter relied upon is located in the provisional application. Appellant contends that the critical reference date of Hauser comes after the appellant's priority date.

Applicant's arguments filed 9/3/10 have been fully considered but they are not persuasive.

The following time-line is an illustration of the priority information of the prior art of Hauser and the instant applications that will be useful in addressing appellant's arguments.



Based on the diagram shown above, appellant argues that the PCT/GB03/03273 and the foreign priority document GB 0217033 provide written description support to the instant application US 10/522,074 by disclosing the instantly claimed sequence SEQ ID NO: 28. Appellant argues that the PCT/IB03/00434 that discloses SEQ ID NO: 37 that comprises the instant SEQ ID NO: 28 provide written description support to the prior art reference US 2006/0241027 (US PGPUB) that has been used in the instant 102(e) rejection that has been maintained during the prosecution. Appellants argue that the provisional application 60/335,547 which forms the basis for the prior art US 2006/0241027 does not disclose the SEQ ID NO: 37 that comprises the instantly claimed SEQ ID NO: 28 and hence does not provide the necessary written description support to the prior art. Therefore, the instant 102(e) rejection is improper.

It should be noted that the SEQ ID NO: 37 of the Figure 2 of Hauser that anticipates the instant invention has an identifying term 'T-1249' associated with the sequence as disclosed in both US 2006/0241027 and PCT/IB03/00434 of Hauser. The term 'T-1249' appears in the instant specification on page 8, line 12 and in the instant foreign priority document PCT/GB03/03273 on page 8 and line 14. The term 'T-1249' also appears in a currently pending US application US 12/401,241 (US 2009/0227775 A1) with a common inventor and common assignee that discloses SEQ ID NO: 37 and the associated term T-1249 (page 34). The currently pending US application US 12/401,241 (US 2009/0227775 A1) claims priority benefit to the same provisional application US 60/355,547 which forms the same priority document to Hauser

2006/0241027 (US PGPUB). Hence, Appellant's argument that Hauser 2006/0241027 (US PGPUB) lacks adequate written description support to anticipate the instant application is not persuasive in light of the supporting evidence as illustrated here. Hence, from the afore-described evidence, it is clear that Hauser was in possession of SEQ ID NO: 37 that encompass the instantly claimed SEQ ID NO: 28 although it has not been expressly disclosed in the form of a peptide sequence in the provisional application of Hauser, i.e., 60/335,547. The currently pending US application US 12/401,241 (US 2009/0227775 A1) claims 'T-1249' sequence in currently pending claim 6. As mentioned earlier the US application US 12/401,241 claims benefit to the same provisional application, i.e., US 60/355,547 as the Hauser.

For the above reasons, it is believed that the rejections should be sustained.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

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